#22/Brief
8/25/02

Express Mail No.: EL 500 575 533 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Nehls et al.

Application No.: 09/428,674 Group Art Unit: 1631

Filed: October 27,1999 Examiner: Marschel, Ardin H.

For: NOVEL HUMAN POLYNUCLEOTIDES AND THE POLYPEPTIDES ENCODED THEREBY

Attorney Docket No.: 8535-029-999

BRIEF ON APPEAL FEE TRANSMITTAL

Assistant Commissioner for Patents
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Washington, D.C. 20231

Sir:

An original and two copies of the applicant's Brief on Appeal in the above-entitled application are submitted herewith. The item(s) checked below apply:

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- ☒ Required.
- ☐ Not required (Fee paid in prior appeal).

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Respectfully submitted,

By: X Liubang 40,258

Date August 15, 2002

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Enclosure

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APPELLANTS' BRIEF ON APPEAL

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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §§ 1.191 AND 1.192

Pursuant to the provisions of 37 C.F.R. §§ 1.191 and 1.192, an appeal is taken herein from the final rejection of claims 3 and 10-14 of this application. Appellants submit an original and two copies of (1) this appeal brief and (2) a Substitute Amendment and Response Under 37 C.F.R. § 1.116. Appellants submit concurrently a Petition for Extension of Time (in duplicate) for four months from April 15, 2002 up to and including August 15, 2002; and a Brief on Appeal Fee Transmittal. The Substitute Amendment is submitted in lieu of the previously filed, but unentered amendment dated February 15, 2002, after the final rejection. The Substitute Amendment obviates the rejections under 35 U.S.C. §§101 and 112, and thus, reduces the issues involved in this appeal. Therefore, entry of the Substitute Amendment is requested. The unentered amendment, dated February 15, 2002, is hereby withdrawn. Appellants also submit herewith Exhibit A: an appendix of the claims (*i.e.*, claims 3, and 10-14) under appeal, as amended in the Substitute Amendment filed concurrently herewith.

I. REAL PARTY IN INTEREST

Appellants have assigned the entire right and interest in the instant application to Lexicon Genetics Incorporated, 8800 Technology Forest Place, The Woodlands, Texas, 77381.

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II. RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any other appeals or interferences which will directly affect, or be directly affected by, or having a bearing on the Board's decision in the present appeal.

III. STATUS OF CLAIMS

Original claims 1-4 of this application were elected for prosecution and non-elected claims 5-9 were withdrawn from consideration by the Examiner. Claims 1, 2, and 4 were canceled without prejudice; claim 3 was amended; and new claims 10, 11, 12, 13, and 14 were added in an Amendment filed on May 21, 2001. Claims 3, and 10-14 have been finally rejected in an Office Action mailed August 15, 2001. Claim 14 was further amended in an Amendment filed on February 15, 2002. The Amendment dated February 15, 2002 was not entered and is hereby withdrawn. A Notice of Appeal was filed on February 15, 2002 appealing the rejection of claims 3, and 10-14.

IV. STATUS OF AMENDMENTS

Subsequent to the final rejection (Final Office Action dated August 15, 2001), Appellants submitted an amendment under Rule 116 in an attempt to secure allowance of claims; the amendment was not entered on the grounds that new issues were presented requiring further consideration and/or search. The Advisory Action stated that the proposed amendment to claim 14 raises new issues including new matter as support have not been found in the section pointed to nor in surrounding pages. (Advisory Action dated June 10, 2002).

The Appellants hereby withdraw the February 15, 2002 unentered amendment.

The Substitute Amendment submitted herewith is offered in lieu of the unentered, withdrawn amendment. The Substitute Amendment, obviates the rejections under 35 U.S.C. §§ 101 and 112, and thus, reduces the issues involved in this appeal. The Appellants' Brief On Appeal is directed to claims 3, 10, 11, 12, 13, and 14. A copy of the claims involved in this Appeal, as amended in the Substitute Amendment filed concurrently herewith, is presented in the attached Exhibit A.

V. SUMMARY OF THE INVENTION

The present invention, as described and claimed, relates to oligonucleotides and polynucleotides that are disclosed as SEQ ID NOS:9-18 in the Sequence Listing. These oligonucleotides and polynucleotides are discovered using gene trap technology in human teratocarcinoma cells.

Teratocarcinoma cells are the "stem cells" that occur in unusual germ cell tumors and represent a good model for molecular mechanisms of embryonic development and differentiation. These cells generate almost any kind of tissues such as teeth, hair, bone, muscle, and cartilage. Stem cells possess the ability both to produce identical daughter cells (self-renewal), and to produce progeny with more restricted fates (commitment and differentiation). This property of stem cells underpins growth and diversification during development and sustains homeostasis and repair processes throughout adult life. An understanding of molecular mechanisms which govern stem cell fate is therefore of fundamental significance in cell and developmental biology and the capabilities arising from such knowledge have major biomedical applications.

According to the invention, the gene trap vectors used in the invention integrate into intron sequences of cellular genes (the "trapped genes") in a genome and produce two fusion transcripts. See page 4, lines 9-13; page 66, lines 13 to page 67, line 19; and Figures 1A-1C. The first fusion transcript comprises exons(s) upstream from the interrupted cellular gene and the coding region of a selectable marker (neomycin resistance was used to produce the presently described oligonucleotides and polynucleotides) from the vector. A mature transcript is generated when the splice donor (SD) and splice acceptor (SA) as shown in Figure 1C are spliced together. Translation of this transcript produces a fusion protein that allows for the selection of cells comprising an integrated gene trap vector.

The second fusion transcript comprises exon 1 of the murine btk gene from the vector which is fused with exons of the trapped gene that are located downstream of the integration site. Unlike the first fusion transcript, transcription of this transcript is under the control of a vector-borne promoter (such as the PGK promoter), and the corresponding mRNA is generated by splicing between the splice donor (SD) and splice acceptor (SA) sites as shown in Figure 1B. To facilitate isolation of the trapped genes, cDNA was generated by reverse transcription of isolated RNA from pools of human teratocarcinoma cells that have undergone independent gene trap events. Based on the unique sequences present in the first

exon of the murine btk gene, selective cloning of the fusion transcript is achieved as shown in Figure 1D and as described on page 67, line 8 to page 68, line 5.

Example 6 (pages 66-71; Figures 1A-1D) demonstrated the identification of oligonucleotides and polynucleotides from human teratocarcinoma cells comprising the claimed nucleic acid sequences of SEQ ID NOS:9-18.

VI. ISSUES

The following issues are presented for review in this appeal:

A. UTILITY

(1) Whether claims 3 and 10-14 lack patentable utility under 35 U.S.C. § 101 for the lack of a specific, substantial, and credible utility. In the Office Actions dated November 21, 2000 and August 15, 2001, the Examiner contended:

(a) that claims 3 and 10-14 are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid;

(b) that the claimed nucleic acid molecules are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter; and

(c) since the claimed invention is not supported by a specific and substantial asserted utility, credibility has not been assessed.

As discussed below, the Examiner's contentions are in error, and the rejection should be reversed.

(2) Whether claims 3 and 10-14 lack patentable utility under 35 U.S.C. § 112, first paragraph. In the Office Actions dated November 21, 2000 and August 15, 2001, the Examiner contended that since claims 3 and 10-14 are not supported by either a specific or substantial utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

As discussed below, the Examiner's contention is in error, and the rejection should be reversed.

B. WRITTEN DESCRIPTION

Whether claims 3 and 10-14 contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention under 35 U.S.C. § 112, second paragraph. In the Office Actions dated November 21, 2000 and August 15, 2001, the Examiner contended that while the specification discloses SEQ ID NOS:9-18, the specification provides insufficient written description to support the genus of nucleotide sequences that comprise SEQ ID NOS:9-18 or hybridize to SEQ ID NOS:9-18 which are encompassed by claims 3 and 10-14.

As discussed below, the Examiner's contention is in error, and the rejection should be reversed.

VII. GROUPING OF CLAIMS

A. UTILITY UNDER 35 U.S.C. § 101

Claims 3 and 10-14 stand rejected under 35 U.S.C. § 101 for the lack of a specific, substantial, and credible utility. Appellants believe that with regard to the issue of utility under 35 U.S.C. § 101, claims 3, 4, and 10-14 stand or fall together.

B. UTILITY UNDER 35 U.S.C. § 112

Claims 3 and 10-14 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of utility. Appellants believe that with regard to the issue of utility under 35 U.S.C. § 112, first paragraph, claims 3, and 10-14 stand or fall together.

C. WRITTEN DESCRIPTION

Claims 3 and 10-14 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Appellants believe that with regard to the issue of written description under 35 U.S.C. § 112, first paragraph, claims 3, and 10-14 stand or fall together.

VIII. ARGUMENTS

A. UTILITY OF THE REJECTED CLAIMS

Claims 3 and 10-14 are drawn to oligonucleotides or polynucleotides that comprise the nucleotide sequences of SEQ ID NOS:9-18 or that hybridize to oligonucleotides or polynucleotides that comprise such nucleotide sequences. These claims have been rejected under 35 U.S.C. § 101.

According to 35 U.S.C. § 101, whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter may obtain a patent therefor subject to the conditions and requirements of 35 U.S.C. The threshold of utility is not high. *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700, 1702 (Fed. Cir. 1999). An invention is "useful" under 35 U.S.C. § 101 if it is capable of providing some identifiable benefit. *Id.* (*citing Brenner v. Manson*, 383 U.S. 519, 534, 148 USPQ 689, 695 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (U.S., 1980)).

It has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). The specification provides numerous specific, substantial, and credible utilities for the claimed nucleic acids comprising SEQ ID NOS:9-18. For instance, at page 7, lines 16-17, the specification describes the utility of polynucleotides or oligonucleotides comprising SEQ ID NOS:9-18 for physical and genetic mapping of the human genome and/or the genome of model organisms. As explained in more detail below, the claimed nucleic acids can be used

as probes, for example, in Northern blot analysis, or in situ hybridization, for different lineages or different stages of differentiation and development.

(1) THE REJECTED CLAIMS HAVE SPECIFIC UTILITY

In particular, the Examiner has based the rejection of claims 3 and 10-14 on the contentions that the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid (*See* Office Action dated August 15, 2001, page 6, lines 12-15; and Office Action dated November 21, 2000, page 5, lines 28-31).

According to the Examination Guidelines for the Utility Requirement ("Examination Guidelines"), if the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 FR 1098 Jan. 5, 2001).

> "A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record."

The definition of specific utility may be found in the Revised Interim Utility Guidelines Training Materials. Specific utility is:

> "a utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed." (Http://www.uspto.gov/web/menu/utility)

Unlike the example cited in the above definition where any fragment of genomic DNA can in theory be used as a probe or a chromosome marker, the polynucleotide sequences of SEQ ID NOS:9-18 have utilities that are not common to any gene in the genome.

Appellants submit that contrary to the Examiner's contention, the polynucleotide sequences of SEQ ID NOS:9-18 have specific utilities which stem from their origin and method of identification. As explained in the Summary of The Invention hereinabove, gene trap vectors were introduced into human teratocarcinoma cells which led

to the identification of gene loci that comprise the sequences set forth in SEQ ID NOS: 9-18. Appellants point out that, as the gene trap vector were introduced into the human teratocarcinoma cell, they integrated into the cell's genome resulting in gene fusions. Each fusion produces a transcript that comprises one or more exons that are located either upstream or downstream from the integration site. These exons, which are portions of a genetic locus that was disrupted by a gene trap vector, are represented by the presently claimed oligonucleotides and polynucleotides.

Appellants respectfully point out that the genetic loci in the teratocarcinoma cells which have been identified by the gene trap vectors fall within a specific class of genes which are distinct from the broad general class of genes in the genome. During the gene identification process teratocarcinoma cells were transfected with the gene trap vectors, some teratocarcinoma cells survived and propagated in culture under selection. These surviving cells each contains a gene, one allele of which is interrupted by the gene trap vector and the other one remains functional. Thus, it is apparent that this gene (and others in this class) encode genetic functions, the full complement of which are <u>not</u> critically essential to the survival and early growth of teratocarcinoma cells. Essentially, these genes are preselected by the transfection and the ensuing cell culture process for possessing functions that are involved in later stages of cell differentiation and development. Appellants emphasize that the sequences set forth in SEQ ID Nos: 9-18 are not identified from the human genome randomly, rather, they represent a sample of genetic sequences that play a role in the later stages of cellular differentiation and development.

Accordingly, the utility of these sequences are not general because not every gene in the genome, when disrupted, necessarily provide the specific utility of the oligonucleotides and polynucleotides of the invention.

After considering the above arguments presented in the amendment dated February 15, 2002, the Examiner stated in the advisory action dated June 10, 2002 that Applicants have not differentiate the myriad of non-essential genes nor isolated with control samples to compare or define any specificity. In response, Appellants point out that the Examiner's suggestion of differentiating the functions of each member of this class of genes amounts to a requirement of exquisite specificity which exceeds that which is required to establish utility according to applicable case law or the Guidelines. Appellants also submit that the transfected cells that may serve as control samples are not preserved by the gene

identification process. This is because genes that are critically essential to the survival of teratocarcinoma cells would not have been isolated and propagated by the gene trap methods of the invention. Cells bearing disruptions in such a class of essential genes would not by definition have been able to survive after transfection with the gene trap vector. Appellants respectfully reiterate that the utility of the claimed nucleic acids in studying teratocarcinoma or stem cell development is not shared by every gene in the genome, and has therefore a specific utility.

In view of the foregoing, Appellants submit that the utilities of the claimed oligonucleotides and polynucleotides are specific. The specific utilities of the claimed oligonucleotides and polynucleotides are further discussed hereinbelow where it is shown that the utilities are substantial and credible.

(2) THE REJECTED CLAIMS HAVE SUBSTANTIAL AND CREDIBLE UTILITY

Appellants submit that the specification provides numerous substantial and credible utilities for polynucleotides or oligonucleotides comprising SEQ ID NOS:9-18.

In the context of the utilities that are specific to the claimed polynucleotides or oligonucleotides, the claimed oligonucleotides and polynucleotides can be used as probes to facilitate the analysis of genetic loci that play a role during specific stages of embryonic development and cell differentiation. As discussed earlier, since the genetic loci and the products encoded by these loci are preselected for the regulation in later stages of teratocarcinoma cell differentiation and development, the claimed oligonuceotides and polynucleotides can be used as probes in hybridization assays well known in the art to determine the activity at the genetic loci during development and differentiation of the teratocarcinomas (*See* for example, page 10, lines 29-33; page 28, lines 24-33; page 36, line 8 to page 37, line 19).

Teratocarcinomas are totipotent which means that they may be differentiated into many different cell types (such as teeth, hair, bone, muscle and cartilage) along various pathways upon induction by certain signals. Each of these pathways may require expression of one or more genes that are disclosed in the specification as filed and represented by the presently claimed oligonucleotides and polynucleotides. Thus, the claimed oligonucleotides and polynucleotides can be used as probes, for example, in Northern blot analysis (page 36, lines 8-11), or in situ hybridization (page 36, lines 11-15), for undifferentiated

teratocarcinomas or differentiated teratocarcinomas of different lineages or at different stages of differentiation and development. The expression pattern of each of these genes can thus be correlated with known events that occur in particular stages of development and cell differentiation. As such, the utility is substantial and credible in a real world context.

The polynucleotides or oligonucleotides of the invention can also be used for diagnostic gene expression and analysis, for cross species hybridization analysis, antisense inhibition, gene targeting, identifying exon splice junctions, gene therapy, gene delivery and chromosome mapping. *See*, for example, page 10, lines 29-33; page 34, line 22 to page 41, line 12.

Furthermore, the gene trapped sequences of the present invention overcome some of the limitations of conventional cDNA and expressed sequence tag libraries. In particular, the claimed oligonucleotide and polynucleotide sequences were identified using gene trap vectors that do not rely solely on the degree of endogenous mRNA expression of a gene for identification of that gene. The gene trap vectors are able to identify poorly expressed genes.

Appellants submit that the above described utilities are well known in the art, and hence utilities of the present invention are credible. As stated in the Examination Guidelines for the Utility Requirement, credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure or any other evidence of record (66 FR 1098, Jan. 5, 2001). Accordingly, not only do the oligonucleotides and polynucleotides of the present invention have specific utilities, their utilities are credible and practical.

In view of the foregoing, Appellants submit that the claimed invention has specific, substantial and credible utility.

B. THE REJECTED CLAIMS HAVE UTILITY UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 3 and 10-14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking utility.

The Federal Circuit and its predecessor have determined that the utility requirement of Section 101 and the how to use requirement of Section 112, first paragraph, have the same basis – the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); *see also In re Jolles*, 628 F.2d 1322, 1326

n.11, 206 USPQ 885, 889 n. 11 (CCPA 1980); and *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971).

Appellants traverse this rejection on the ground that Claims 3 and 10-14 have significant patentable utility as discussed in Section A, above. Appellants submit that when an Appellant satisfactorily rebuts a rejection based on a lack of utility under 35 U.S.C. § 101, the corresponding rejection imposed under 35 U.S.C. § 112, first paragraph, should also be withdrawn.

C. THE REJECTED CLAIMS AND THE SPECIFICATION MEET THE WRITTEN DESCRIPTION REQUIREMENT

Claims 3 and 10-14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification. The Examiner alleges that claims 3 and 10-14 are directed to gene sequences *comprising* and sequences that *hybridize* to SEQ ID NOS:9-18, and that only SEQ ID NOS:9-18 but not the full breadth of the claim meet the written description requirement. The Examiner contends that the species specifically disclosed are not representative of the genus because the genus is highly variant. The rejection is erroneous.

According to applicable case law, an applicant must convey with reasonable clarity to those skilled in the art that the applicant was in possession of the invention. *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, 5 USPQ2d 1194, 1197 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988).

Claims 3 and 10-14 recite isolated oligonucleotides or polynucleotides corresponding to one of SEQ ID NO:10-18. The isolated oligonucleotides or polynucleotides are fully described by *structure* or by *physical properties*, or both, sufficient to distinguish the claimed isolated oligonucleotides or polynucleotides from other materials. For instance, Claim 3 recites isolated oligonucleotides that comprise a contiguous stretch of at least about 60 nucleotides of at least one of SEQ ID NO:10-12, 15, or 16. As the exact structure of SEQ ID NOS:10-12, 15, and 16 are provided in the specification, although there are numerous oligonucleotides that falls within this description, one person of skilled in the art can readily recognizes the synthetic oligonucleotide as described in claim 3. Likewise,

claim 14 describes a genus of polynucleotides by a property (i.e., hybridizable under defined conditions to known sequences) that readily distinguishes the claimed polynucleotides from other materials. One of skill in the art can readily compare a polynucleotide with the claimed polynucleotides of Claim 14 by performing a hybridization as recited in the claim.

Appellants respectfully point out that the chemical structure of the claimed genus of nucleic acid molecules are described and well known in the art (e.g., DNA, RNA) and that the variation of nucleotide sequence within the claimed genus is also well defined by the functional characteristics of specifically binding under defined hybridizing conditions to nucleic acid molecules of known sequences. According to the Examination Guidelines Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement (66 FR 1099-1111, Jan. 5, 2001), the written description requirement may be satisfied by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See footnote 42 of the Examination Guidelines wherein it is stated that examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length, and also detailed restriction enzyme maps, antibody cross-reactivity, unique cleavage by particular enzymes. One of skill in the art would recognize from the combination of identifying structural and functional characteristics disclosed in the specification that Appellants have possession of the claimed genus of nucleic acid molecules. In fact, the skilled person can readily recognize and determine whether a nucleic acid molecule falls within the pending claims by either comparing the sequence of the molecule with the sequences provided in the application and/or performing a hybridization reaction under defined conditions with the nucleic acid molecule(s) described in the present application. As such, Appellants submit that adequate written description has been provided.

The Examiner alleges that there is no description of other elements included in DNA, such as non-coding, regulatory regions, etc. Appellants submit that the term "comprising" is a term of art that is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987); *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (Pat. Bd. App. 1948) ("comprising" leaves "the claim

open for the inclusion of unspecified ingredients even in major amounts"). The specification discloses exemplary elements that may be included in the claimed oligonucleotides or polynucleotides, such as non-coding or regulatory regions (page 20, lines 22-32); vector sequences (page 23, line 17 to page 25, line 32), other coding sequences as obtained by "primer extension" (page 9, lines 16-21). As such, the specification is replete with description of representative elements that may be included in the claimed oligonucleotides and polynucleotides. Appellants submit that the written description requirement for the claimed genus of molecules are met.

IX. CONCLUSION

For the reasons set forth above, Appellants respectfully request that the rejection of the claims on appeal under 35 U.S.C. §§ 101 and 112 be reversed.

Respectfully submitted,

By: J Chris Tsang 40,258

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Date: August 15, 2002

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